

# Advancing Laboratory Interoperability in Health IT

## Introduction & CDC LabHIT Update

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Clinical Laboratory Improvement Advisory Committee (CLIAC)

8-22-2013

Center for Surveillance, Epidemiology, and Laboratory Services (proposed)

Division of Laboratory Programs, Standards, and Services (proposed)



## Background

- **The Health Information Technology for Economic and Clinical Health (HITECH) Act**
  - Enacted as part of American Recovery and Reinvestment Act of 2009 (ARRA)
  - Promotes widespread adoption and standardization of health information technology (HIT)
  - Unprecedented investment in HIT
  - Lightning speed advancement of regulations

# Meaningful Use of Health Information Technology

## 2 Sets of “Bookend” Regulations for Electronic Health Records

Working together to ensure quality



### EHR Certification Requirements

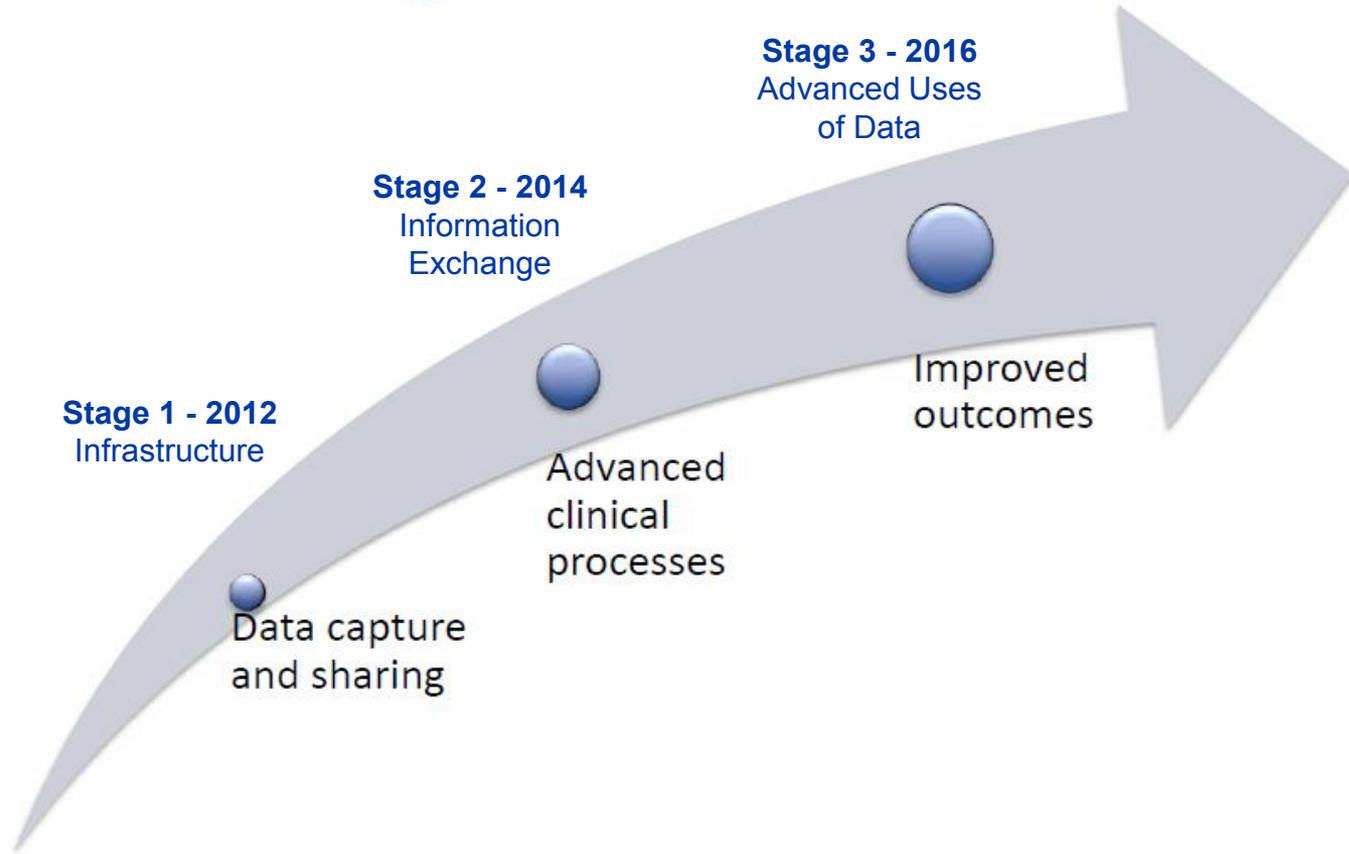
- Regulations overseen by the Office of the National Coordinator (ONC)
- EHR test methods developed and implemented by the National Institute of Standards and Technology (NIST)
- Methods applied by Authorized Testing and Certification Bodies (ATCBs)

### EHR Incentive Program

- Regulations overseen by the Centers for Medicare and Medicaid Services (CMS)
- EHR performance measures are used to determine incentive payments for eligible healthcare providers
- Administered by CMS and State Medicaid Agencies



# A Conceptual Approach to Meaningful Use



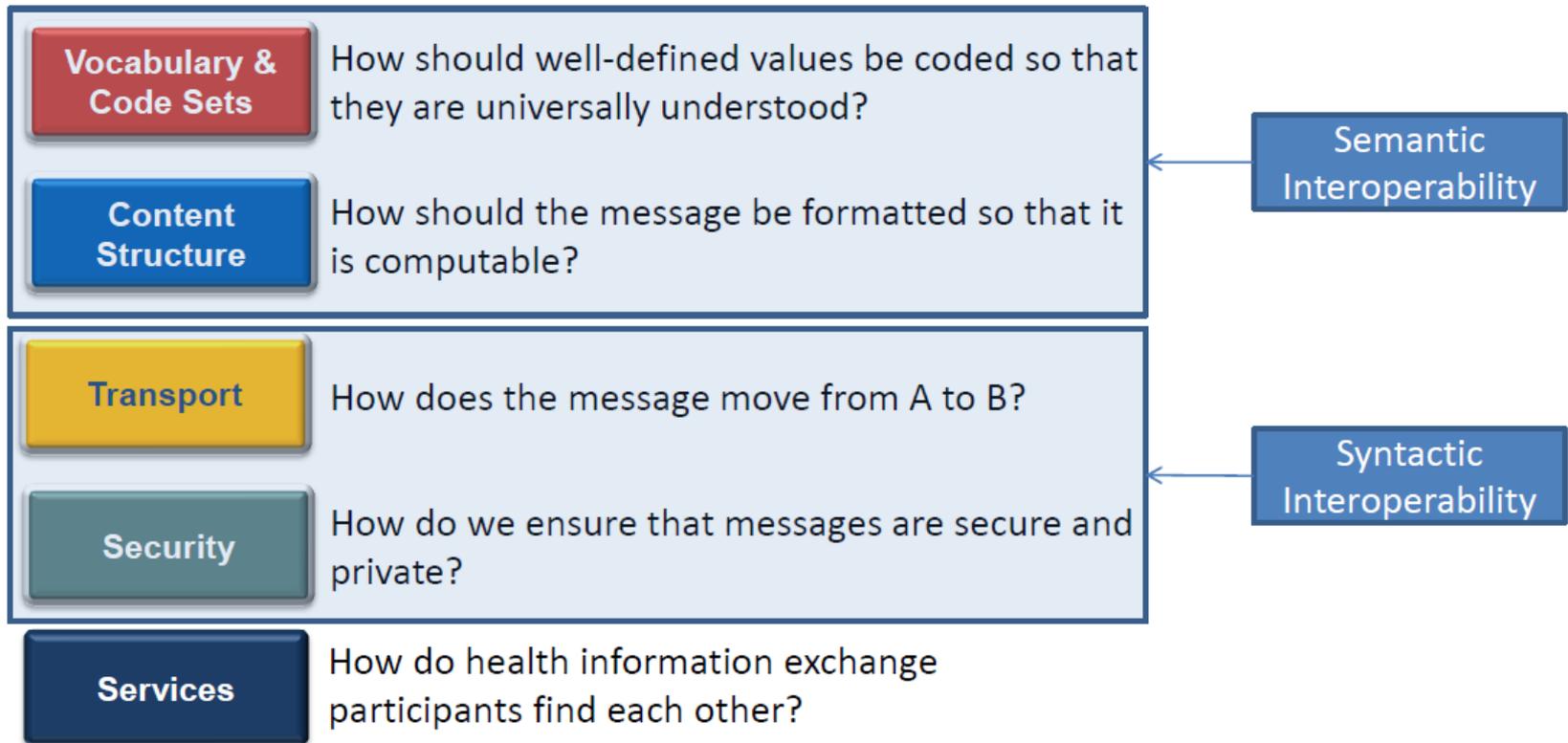
# Overview of Laboratory Data Related Meaningful Use Objectives and EHR Certification Criteria

- **Meaningful Use Objectives**
  - Laboratory Results in EHR
  - Laboratory Results to Ambulatory Providers
  - Lab Orders by Computerized Provider Order Entry (CPOE)
  - Reportable Lab Results to Public Health Agencies
- **EHR Certification Criteria Which Include Laboratory Data**
  - Patient Lists
  - Patient Reminders
  - Clinical Decision Support
  - Patient Specific Education

# Standards Supporting Electronic Transmission of Data

## Standard Interoperability “Building Blocks”

Putting the I in HealthIT  
www.HealthIT.gov



From ONC's Interoperability Strategy presentation, 2013 Government Health IT Conference. Doug Fridsma, Chief Science Officer & Director, Office of Science and Technology. <http://www.govhealthitconference.com/session1-1.aspx>

# Standards Supporting Electronic Transmission of Laboratory Data

## ■ Vocabulary Standards

- Logical Observation Identifiers Names and Codes (LOINC)<sup>®</sup>
  - Version 2.40, June 2012
- Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT)<sup>®</sup>
  - International Release, July 2012 and US Extension to SNOMED CT,<sup>®</sup> March 2012 Release

## ■ Content Structure Standards

- Technical specifications defined in HL7 Implementation Guides
  - HL7 v2.5.1 Lab Orders Interface (LOI)
  - HL7 v2.5.1 Lab Results Interface (LRI)
  - HL7 v2.5.1 Electronic Laboratory Reporting to Public Health (ELR)
  - HL7 Version 3 (Infobutton)

# Meaningful Use Objectives Which Include Laboratory Data

CORE OBJECTIVE	MEANINGFUL USE Stage 2 Objective 42 CFR 495.6(j)-(m)	MEANINGFUL USE Stage 2 Measure 42 CFR 495.6(j)-(m)	EHR CERTIFICATION CRITERIA 2014 Edition 45 CFR 170.314	STANDARDS
Eligible Providers Eligible Hospitals	<b>Lab Results in EHR</b>	> 55% of all clinical lab tests results whose results are either in a positive/negative affirmation or numerical format are incorporated in CEHRT as structured data.	<p>Ambulatory setting:</p> <ul style="list-style-type: none"> <li>Electronically receive and incorporate clinical laboratory tests and values/results in accordance with specified standards.</li> <li>Electronically display the tests and values/results received in human readable format.</li> </ul> <p>Inpatient setting only:</p> <ul style="list-style-type: none"> <li>Electronically receive clinical laboratory tests and values/results in a structured format.</li> <li>Electronically display such tests and values/results in human readable format.</li> <li>Electronically display all the information for a test report specified in CLIA at 42 CFR 493.1291(c)(1) through (7).</li> <li>Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.</li> </ul>	<p>HL7 Version 2.5.1 Lab Results Interface (LRI)</p> <p>LOINC® version 2.40, June 2012 A universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.</p>

Table excerpted from “2014 Edition EHR Certification Criteria and Meaningful Use Objectives” document on the Office of the National Coordinator’s website, retrieved 8-19-13: [http://www.healthit.gov/sites/default/files/meaningfulusetablesseries2\\_110112.pdf](http://www.healthit.gov/sites/default/files/meaningfulusetablesseries2_110112.pdf)

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Eligible Hospitals (Menu item, not Core)	<b>Lab Results to Ambulatory Providers</b>	Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20% of electronic lab orders received.	EHR technology must be able to electronically create laboratory test reports for electronic transmission.	HL7 Version 2.5.1 Lab Results Interface (LRI)  LOINC® version 2.40, June 2012.
Eligible Providers  Eligible Hospitals	<b>Lab Orders by Computerized Provider Order Entry (CPOE)</b>	>30% of laboratory orders	Enable a user to electronically record, change, and access laboratory orders.	HL7 Version 2.5.1 Lab Orders Interface (LOI)
Eligible Hospitals	<b>Reportable Lab Results to Public Health Agencies</b>	Successful ongoing submission of electronic reportable laboratory results from CEHRT to a public health agency for the entire EHR reporting period. *Exclusions apply: see CMS rule for details	EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission.	HL7 2.5.1 Electronic Laboratory Reporting to Public Health (ELR).  IHTSDO SNOMED CT® International Release, July 2012 and US Extension to SNOMED CT,® March 2012 Release.  LOINC® version 2.40, June 2012.

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# EHR Certification Criteria Which Include Laboratory Data

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Eligible Providers  Eligible Hospitals	<b>Patient Lists</b>	Generate at least one report listing patients of the EP, EH, or CAH with a specific condition.	Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on <b>laboratory tests and values/results</b> In Ambulatory setting only, also create lists by patient communication preferences.	HL7 Version 2.5.1 Lab Results Interface (LRI)  LOINC® version 2.40, June 2012
Eligible Providers	<b>Patient Reminders</b>	More than 10% of all unique patients who have had two or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference when available. *Exclusions apply: see CMS rule for details	Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on <b>laboratory tests and values/results</b> . In Ambulatory setting only, also create lists by patient communication preferences.	HL7 2.5.1 Electronic Laboratory Reporting to Public Health (ELR).  IHTSDO SNOMED CT® International Release, July 2012 and US Extension to SNOMED CT,® March 2012 Release.  LOINC® version 2.40, June 2012.

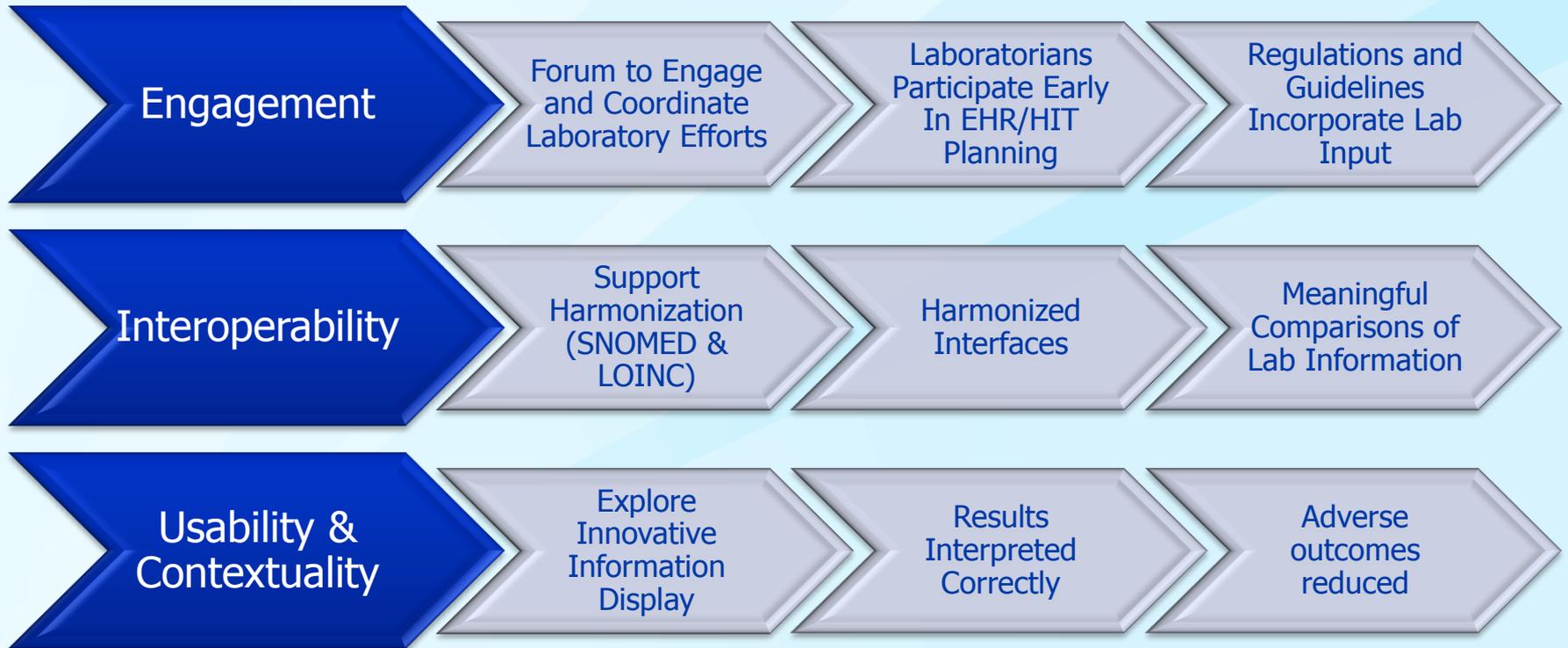
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Eligible Providers Eligible Hospitals	<b>Clinical Decision Support</b>	Implement five clinical decision support interventions related to four or more clinical quality measures. *Exclusions apply: see CMS rule for details	Enable a limited set of identified users to select one or more clinical decision support interventions based on each one and at least one combination of the following data: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) Demographics; <b>(E) Laboratory tests and values/results; and</b> (F) Vital signs.	HL7 Version 3 (Infobutton)
Eligible Providers Eligible Hospitals	<b>Patient Specific Education</b>	EP: Patient-specific education resources identified by CEHRT are provided to patients for more than 10% of all unique patients with office visits. *Exclusions apply: see CMS rule for details  EHs/CAHs: More than 10% of all unique patients admitted to the EH's or CAH's inpatient or emergency departments are provided patient-specific education resources identified by CEHRT.	EHR technology must be able to electronically identify for a user patient-specific education resources based on <b>laboratory tests and values/results.</b>	HL7 Version 3 (Infobutton)

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# **CDC's LabHIT Team Vision:** *Laboratory information contributes to optimized healthcare decision making.*



# LabHIT Activities

- **ONC Laboratory Report Workgroup Tiger Team**
  - Producing recommendations intended to reduce the cost and burden associated with implementing an ambulatory EHR to LIS interface (Laboratory Orders and Laboratory Results Interfaces).
  - Includes the Tiger Team and three subgroups:
    - Policy
    - Standards
    - Certification

# LabHIT Activities

## ■ Content Standards Development and Related Activities

- S&I Laboratory Order Interface (LOI) – HL7 Implementation Guide for EHR vendors
- S&I Laboratory Results Interface (LRI) - HL7 Implementation Guide for EHR vendors
- S&I electronic Directory of Service (eDOS) - HL7 Implementation Guide for EHR vendors
- S&I LOI/LRI CLIA Compliance Workgroup (active)– Crosswalk of CLIA requirements to HL7 field sets to support the Implementation Guides
- NIST CLIA Certification Profile (pending) – Enhance online LRI certification tool for EHR vendors to test for CLIA requirements
- NIST Big Data workgroup (new) – Engaged Dr. Michael Becich (pathology informatics geneticist) from UPenn to participate
- Electronic Laboratory Reporting (not active, ad hoc) – Provided input to improve clinical relevance of certification use cases

# LabHIT Activities

## ■ Content Standards Development and Related Activities

- S&I Health eDecisions (ad hoc)
- S&I Query Health (ad hoc)
- S&I Structured Data Capture (active workgroup – considering resources for LabHIT participation)
- S&I Data Access Framework (active)
- HL7 Variant Call File Transmission (active) – HL7 Implementation Guide for the technical specifications of transmitting molecular genetics files from research laboratory to EHR. (Note this is not an S&I related activity. HL7 is operating this implementation guide workgroup in parallel to CDC's Next Generation Sequencing workgroup activities.)

# LabHIT Activities

## ■ Vocabulary Standards Development

- APHL's Laboratory Community of Practice (ongoing) – Harmonizing and updating SNOMED specimen type coding, map to LOINC
- CDC's Reportable Conditions Cross Mapping Table – Mapping reportable conditions to SNOMED coding
- LOINC Enhancement Project (proposed) – Identifying top 80-90% order code set for ambulatory providers
- Advancing Laboratory Interoperability (draft proposal) – short, mid and long range planning for full-scale semantic interoperability for laboratory data. Vision is to create a single national reference database of recommended vocabulary sets with mapping of FDA approved test systems to vocabulary code systems (e.g. LOINC, SNOMED, UCUM)
- NIH LOINC for Variant Call Files (proposed, pending funding) - Mapping LOINC to molecular genetics terms

***EMAIL THE CDC'S LABHIT TEAM  
IF YOU OR YOUR ORGANIZATION CAN  
PARTICIPATE ON A STANDARDS  
DEVELOPMENT WORKGROUP.***



**LABHIT@CDC.GOV**

# Introduction of Speakers

- **Dr. Doug Fridsma**
  - ONC Chief Science Officer & Director, Office of Science & Technology
- **Mr. Robert Dieterle**
  - ONC Contractor for S&I Framework and Laboratory Tiger Team and CEO EnableCare Group, LLC
- **Dr. Alexis Carter**
  - Director of Pathology Informatics, Emory University School of Medicine
- **Dr. Sundak Ganesan**
  - CDC Health Scientist, Division of Informatics Solutions and Operations
- **Dr. Nancy Cornish**
  - CDC Medical Officer, Division of Laboratory Programs, Standards, and Services (proposed)

# References

- **ONC EHR Incentives and Certification:** <http://www.healthit.gov/providers-professionals/ehr-incentives-certification>
- **ONC Authorized Testing and Certifications Bodies:** <http://www.healthit.gov/policy-researchers-implementers/authorized-testing-and-certifications-bodies>
- **CMS EHR Incentive Program:** <http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHRIncentivePrograms/>
- **NIST Test Methods:** [http://healthcare.nist.gov/use\\_testing/](http://healthcare.nist.gov/use_testing/)
- **Standards & Interoperability Framework:** <http://www.siframework.org/>



*Thank you!*

**For more information please contact Centers for Disease Control and Prevention**

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CLIA Information Line: 1-404-498-2290      TTY: 1-888-232-6348

E-mail: [LabHIT@cdc.gov](mailto:LabHIT@cdc.gov)      Web: <http://wwwn.cdc.gov/clia/>

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Center for Surveillance, Epidemiology, and Laboratory Services (proposed)

Division of Laboratory Programs, Standards, and Services (proposed)

